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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/448,378 11/23/99 BRASEL

K 2836-D

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HM12/0717

EXAMINER

VANDER VEGT, F

ART UNIT

PAPER NUMBER

1644

5

DATE MAILED:

07/17/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/448,378

Applicant(s)

Brasel et al

Examiner

F. Pierre VanderVegt

Group Art Unit

1644



☒ Responsive to communication(s) filed on May 15, 2000

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1, 2, 6, 7, 20, and 22-43 ~~is~~ are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 2, 6, 7, 20, and 22-43 ~~is~~ are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

### DETAILED ACTION

This application is a continuation of application 08/725,540.

Claims 3-5, 8-19 and 21 have been canceled.

New claims 22-43 have been added.

5        Claims 1, 2, 6, 7, 20 and 22-43 are currently pending in this application.

### *Election/Restriction*

1.        Applicant's election without traverse of Group II, claims 1, 2, 6, 7, 20 and 21, in Paper No. 4, filed May 15, 2000, is acknowledged.

10        Applicant submitted new claims 22-43 subsequent to the election of Group II. Claims 22-43 are readable upon the invention of Group II and are therefore included therewith.

Claims 1, 2, 6, 7, 20 and 22-43 are the subject of examination in this Office Action.

### *Specification*

15        2..        The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the Applicant, or a practitioner representing the Applicant, stating that the amendatory material consists of the same material  
20        incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

      The attempt to incorporate subject matter into this application by reference to U.S. Patent No. 5,554,512 is improper because no such affidavit or declaration was filed along with the  
25        amendment.

***Claim Rejections - 35 USC § 112***

3. Claims 22-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 22-39 depend upon the recitation introduced into line 36 of page 4 of the instant specification by the amendment filed May 15, 2000. The claims are reliant upon the recitation as essential material and find no support in the specification or claims as originally filed. As discussed supra, said recitation constitutes new matter, therefore the claims also constitute new matter. The claims must be canceled or the incorporation of the recitation must be perfected in order to overcome the new matter rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the Applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the Applicant for patent.

4. Claim 1, 2, 6, 7, 20 and 40-43 are rejected under 35 U.S.C. 102(a,e) as being anticipated by U.S. Patent No. 5,554,512 to Lyman et al (on form PTO-1449 filed 2/7/2000).

The '512 patent teaches a method for treatment of human patients comprising in vivo administration of Flt-3L (abstract in particular). The '512 patent further teaches that the method is useful for the treatment of human cancer patients (column 3, lines 32-38 in particular). The '512 patent teaches treatment by the same routes and dosages (column 18, line 53 through column 19, line 3) as the routes and dosages taught by the instant specification (page 12, lines 18-29), *verbatim*. While the '512 patent does not disclose the end result of performing the claimed

method *in haec verba*, the increase of dendritic cells, the fact that the exact same method is used indicates that Applicant is claiming a further characterization of an otherwise old method and the increase in dendritic cells is an inherent property of the method taught by the '512 patent. See *Ex parte* Novitski (BdPatApp&Int) 26 USPQ2d 1389. The '512 patent further teaches the combination of Flt-3L treatment of a patient with other cytokines including GM-CSF, IL-4, TNF- $\alpha$ , IL-3, c-kit ligand and GM-CSF/IL-3 fusion proteins [claims 2, 16 and 19-21](column 3, line 45 through column 4, line 4 in particular). The '512 patent also teaches that such combinations of therapeutic cytokines with Flt-3L are useful for the treatment of patients undergoing cytoreductive therapy to counteract the myelosuppressive effects of such therapy (column 3, line 45 through column 4, line 4 in particular). Cytoreductive therapy, which encompasses radiation therapy and chemotherapy, for example, is a common step in the treatment of cancers [claims 18 and 22-24] such as immunoproliferative disorders, i.e., leukemias and lymphomas, which are included among the Flt-3L treatable conditions (column 3, lines 33-39). The prior art teaching anticipates the claimed invention

### *Conclusion*


5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

6. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2000 366-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a

general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

5 F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
Technology Center 1600  
July 12, 2000



**F. PIERRE VANDERVEGT**  
**PATENT EXAMINER**